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10/085,564	02/26/2002	Keith K. Daellenbach	BJT 332	8968

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EXAMINER	
SCHELL, LAURA C	
ART UNIT	**PAPER NUMBER**
3767	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/085,564	DAELLENBACH, KEITH K.	
	Examiner	Art Unit	
	Laura C. Schell	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25,33 and 35-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25,33,35-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/27/07-10/24/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-9, 14, 15, 33 and 40-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tom (US Patent No. 7,211,063) in view of Glines et al. (US Patent No. 6,716,190). Tom discloses a needle-free jet injection device for delivering a fluid into an internal organ (Fig. 1; the abstract and col. 1, lines 16-20 disclose that the device is used for treating an internal organ such as the heart; col. 3, lines 35-40 disclose that the device can be used for needle-free injection), the device comprising: a rigid end effector having a blunt distal end and a longitudinal axis configured into a shape (Fig. 1 discloses that the longitudinal axis of the end effector is bent at a 90 degree angle, the distal end 20 is blunt and col. 3, lines 19-20 disclose that the end

effector has a rigid shaft), the end effector including a rigid interior wall that defines a rigid fluid channel, where the end effector is substantially rigid to maintain the shape of its longitudinal axis during use (Fig. 1, col. 3, lines 19-20), wherein the fluid channel has a cross section through which a central axis of the end effector extends, and where the end effector is configured to enable fluid to flow from the fluid channel out through the orifice (Fig. 1, col. 3, lines 35-40), a fluid reservoir in fluid communication with the end effector (col. 3, lines 44-48 disclose that the apparatus is equipped similarly to other well known devices in order to produce the therapeutic effect, i.e. needle-free injection, and therefore the fluid that is injected must be stored somewhere, thus indicating there must be some sort of fluid reservoir in the device); and an ejection mechanism adapted to eject the fluid from the fluid reservoir through the end effector and out the orifice with sufficient pressure to penetrate the surface of the organ while preserving functionality of the organ and without penetration of the outer surface of the organ by the end effector (col. 2, lines 14-16 discloses that the treatment occurs at the surface of the organ to be treated, Fig. 1 discloses that the end effector is placed against the surface of the organ (47); and col. 3, lines 35-48 disclose that the device can be sued for needle-free injection and would include all the necessary equipment as in known in the art, therefore it would have to include an ejection mechanism; col. 2, lines 1-7 discloses that the treatment preserves the functionality of the tissue by safely treating the tissue and avoiding perforation-type injuries to the tissue), where the end effector extends away from the ejection mechanism such that an operative end of the end effector is spaced from the ejection mechanism (Fig. 1).

Tom, however, does not disclose that the end effector includes a plurality of orifices. Glines, however, discloses a similar needle-free jet injection device (Figs. 8a-8c, for example) that includes a blunt distal end (230), a fluid channel (223), a fluid reservoir (within 215), an ejection mechanism (within 202) as well as the blunt distal end of the end effector having a plurality of orifices (Fig. 8c, 232). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Tom's end effector with a plurality of orifices, as taught by Glines, as Tom discloses that the device may include parts that are well known in the art in order to accomplish the therapeutic treatment of needle-free injection (col. 3, lines 35-48) as well as to provide a treatment that covers a larger surface area so fewer individual treatments are needed.

In reference to claim 2, Tom discloses that the end effector includes a straight shaft section and a distal section (Fig. 1).

In reference to claims 3 and 4, Tom discloses that at least one of the orifices are located in the distal section (Fig. 1), while Glines discloses that all of the orifices are located in the distal section (Fig. 8c).

In reference to claim 5, Glines discloses that the ejection mechanism is further adapted to allow the device to eject multiple doses of fluid without refilling the reservoir (col. 13, lines 51-54 discloses that the reservoir is configured to hold at least one dose but can also be configured to hold multiple doses as needed).

In reference to claims 6, 7 and 9, Tom discloses that the device is used as such a pressure that the fluid is ejected through the orifice to cause a transmural lesion in the

organ, such as the heart (the abstract and col. 1, lines 16-61 disclose that the device is used for treating the wall of the heart, while col. 2, lines 1-7 disclose that the device prevents peforation of the organ wall).

In reference to claim 8, Glines discloses a needle-free jet injection device which delivers ethanol (col. 18, lines 29-32). Therefore it would have been obvious to one of ordinary skill in the art to have used the needle-free jet injection device of Nash to deliver ethanol, as taught by Glines, because ethanol is fluid that is particularly useful to inject into tissues, particularly to ablate a tissue at the site of the jet injector.

In reference to claim 14, Tom discloses that the distal section lies at an angle between 30 and 90 degrees relative to the shaft (Fig. 1).

In reference to claim 33, Tom discloses that the fluid channel is cylindrical (Figs. 1 and 2).

In reference to claim 40, Glines discloses that the longitudinal axis of the distal section is collinear with a longitudinal axis of the straight shaft section (Figs. 8a-8c).

In reference to claim 41, Tom discloses that a portion of the longitudinal axis of the distal section is not collinear with a longitudinal axis of the straight shaft section (Fig. 1).

In reference to claim 42, Tom discloses that at least a portion of the longitudinal axis of the distal section lies at an angle between 30 and 90 degrees relative to at least a portion of the longitudinal axis of the straight shaft section (Fig. 1).

In reference to claims 15 and 43, Glines discloses a portion of the longitudinal axis of the distal section lies at an angle of approximately 45 degrees relative to the longitudinal axis of the straight shaft section (Fig. 8d).

Claims 19, 20 and 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tom (US Patent No. 7,211,063) in view of Glines et al. (US Patent No. 6,716,190). Tom discloses an end effector for a needle-free injection device adapted to inject a fluid through an outer surface of an internal organ and into the internal organ (Fig. 1; the abstract and col. 1, lines 16-20 disclose that the device is used for treating an internal organ such as the heart; col. 3, lines 35-40 disclose that the device can be used for needle-free injection), without penetration of the outer surface of the internal organ by the end effector (col. 2, lines 14-16 discloses that the treatment occurs at the surface of the organ to be treated, Fig. 1 discloses that the end effector is placed against the surface of the organ (47)), while maintaining functionality of the organ (col. 2, lines 1-7 discloses that the treatment preserves the functionality of the tissue by safely treating the tissue and avoiding perforation-type injuries to the tissue), the end effector comprising a longitudinally rigid elongate shaft that extends away from the injection device to a blunt distal end (Fig. 1 discloses that the longitudinal axis of the end effector is bent at a 90 degree angle, the distal end 20 is blunt and col. 3, lines 19-20 disclose that the end effector has a rigid shaft) and that includes a tubular fluid channel fluidly and directly coupled with an orifice through which the fluid may be

ejected (Fig. 1, col. 3, lines 19-20), where the elongate shaft is sufficiently rigid to maintain a longitudinal shape with use, where the tubular fluid channel has a cross section through which a central axis of the end effector extends, and where the tubular fluid channel includes a rigid portion extend substantially all the way between the injection device and the orifice (Fig. 1; col. 3, lines 19-20).

Tom, however, does not disclose that the end effector includes a plurality of orifices. Glines, however, discloses a similar needle-free jet injection device (Figs. 8a-8c, for example) that includes a blunt distal end (230), a fluid channel (223), a fluid reservoir (within 215), an ejection mechanism (within 202) as well as the blunt distal end of the end effector having a plurality of orifices (Fig. 8c, 232). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Tom's end effector with a plurality of orifices, as taught by Glines, as Tom discloses that the device may include parts that are well known in the art in order to accomplish the therapeutic treatment of needle-free injection (col. 3, lines 35-48) as well as to provide a treatment that covers a larger surface area so fewer individual treatments are needed.

In reference to claim 20, Tom discloses a straight shaft section and a distal section (Fig. 1).

In reference to claims 22 and 23, Tom discloses that at least one of the orifices are located in the distal section (Fig. 1), while Glines discloses that all of the orifices are located in the distal section (Fig. 8c).

In reference to claims 24 and 25, Tom discloses that the distal section is angled relative to the straight section and that distal section is curved (Fig. 1).

Claims 10-13 and 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tom (US Patent No. 7,211,063). Tom discloses the device substantially as claimed including that the device is used for needle-free injection, which by definition occurs at higher pressures in order to produce enough force on the fluid to eject into the tissue (col. 3, lines 35-40). Tom, however, does not disclose the specific pressures of less than 4000, 2100 or 1100 psig nor the specific dimensions of the device, such as specific lengths and diameters of parts. It would have been obvious to one of ordinary skill in the art to eject fluid from the device at pressures less than 4000, 2100 or 1100 psig, and the claimed lengths and diameters since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980)

Claims 16-18 and 21, 35, 36 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tom (US Patent No. 7,211,063) in view of Paskar (US Patent No. 6,623,449). Tom discloses the device substantially as claimed including orifice on the end effector (Figs. 1 and 2). Tom further discloses that all of the orifices are located in the distal section (Fig. 1). Tom also discloses that the distal section is curved and angled relative to the straight section (Figs. 1). However, Tom does not disclose that the

orifices are arranged along the length of the end effector or how they are arranged in rows. Paskar, however, discloses an end effector (Fig. 16) which has orifices (134) arranged in multiple offset rows along the length of the end effector. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Tom's end effector with the arrangement of orifices, as taught by Paskar, in order to provide a device which could be used to cover and treat more area of the tissue and thus provide a faster and more efficient treatment.

Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Menne et al. (US Patent No. 5,840,061) in view of Tom (US Patent No. 7,211,063). Menne discloses a needle-free jet injection device (Fig. 3) for delivering a fluid into a selected internal tissue, the device comprising a body (Fig. 3); a longitudinally rigid elongate member (9) extending away from the body to a blunt distal end (distal end near 17 is blunt), the longitudinally elongate member comprising: a sidewall (sidewall where 2 is located), a central longitudinal axis configured into a shape (Fig. 3), wherein the longitudinally rigid elongate member is sufficiently rigid to maintain the shape of its central longitudinal axis during use (Fig. 3), at least one injection orifice (2) disposed on the sidewall, wherein the at least one injection orifice is oriented generally laterally to the central longitudinal axis (Fig. 3), a fluid channel (1) extending substantially all the way from the body to the at least one injection orifice, wherein the fluid channel has a cross section through which the central longitudinal axis extends (fig. 3), a straight shaft

section (Fig. 3), and a distal section (distal section is near 2), at least one injection orifice (2) is disposed on the distal section, and the longitudinally rigid elongate member is adapted to be positioned with the at least on injection orifice adjacent the selected internal tissue; a fluid reservoir (the fluid reservoir is connected at 19 as described in col. 5, lines 7-8) in communication with the fluid channel; and an ejection mechanism (Fig. 1,4 is the piston/ejection mechanism) disposed within the body, wherein the ejection mechanism is adapted to eject the fluid from the fluid reservoir through the fluid channel and out the at least one injection orifice with sufficient pressure to penetrate the selected internal tissue (col. 1, lines 50-55) while preserving functionality of the tissue and without penetration of the selected internal tissue by the longitudinally rigid elongate member (col. 6, lines 41-42). Menne, however, does not disclose that the distal end of the device is not collinear with the longitudinal axis of the straight shaft section. Tom, however, discloses a needle-free jet injection device in which the distal section is bent at an angle relative to the straight shaft section (Fig. 1). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Menne by bending the distal portion of the device at an angle relative to the straight shaft section, as taught by Tom, in order to provide a device which can reach portions of the body which can not be reached by a device that is not bent, thereby increasing the number of treatment areas and types of treatment that are possible with the device.

Response to Arguments

Applicant's arguments with respect to claims 125, 33, 35-45 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Schell whose telephone number is (571) 272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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LCS

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

Kevin C. Sirmons